



## **Amarin Announces FDA Advisory Committee Will Not Be Scheduled in Connection With New Drug Application for AMR101**

BEDMINSTER, N.J. and DUBLIN, Ireland, Feb. 13, 2012 (GLOBE NEWSWIRE) -- Amarin Corporation plc (Nasdaq:AMRN), a late-stage biopharmaceutical company with a focus on cardiovascular disease, announced today that it was informed by the U.S. Food and Drug Administration (FDA) that no advisory committee meeting will be scheduled in connection with the FDA's review of the New Drug Application (NDA) seeking approval for the use AMR101 in the treatment of patients with very high triglycerides ( $\geq 500$ mg/dL), the company's lead product candidate. The FDA has previously assigned a Prescription Drug User Fee Act (PDUFA) date of July 26, 2012 for completion of its review of the AMR101 NDA.

### **About AMR101**

AMR101 (icosapent ethyl), is a prescription-grade omega-3 fatty acid, comprising not less than 96% ultra pure EPA (icosapent ethyl) that Amarin is developing for the treatment of patients with very high triglyceride levels ( $\geq 500$  mg/dL) and of patients with high triglyceride levels ( $\geq 200$  and  $< 500$ mg/dL) who are also on statin therapy for elevated low-density lipoprotein cholesterol, or LDL-C, levels (which we refer to as mixed dyslipidemia). The efficacy and safety of AMR101 were studied in two Phase 3 clinical trials, the MARINE trial, which studied patients with very high triglyceride levels, and the ANCHOR trial, which studied patients with high triglyceride levels who were also on statin therapy for elevated LDL-C levels. These two Phase 3 clinical trials showed favorable results in triglyceride reduction compared to placebo in the studied patient populations. Reduction in triglyceride levels was achieved without a statistically significant increase, and in the 4 gram AMR101 ANCHOR results, with a statistically significant decrease, in LDL-C levels. These trials also showed favorable results, particularly with the 4 gram dose of AMR101, in other important lipid and inflammation biomarkers, including Apo-B, non-HDL-C, Total-Cholesterol, VLDL-C, Lp-PLA2, and hs-CRP. In these trials, AMR101 exhibited a safety profile comparable to placebo.

### **About Amarin**

Amarin Corporation plc is a late-stage biopharmaceutical company with expertise in lipid science focused on the treatment of cardiovascular disease. Amarin has filed a New Drug Application (NDA) with FDA for the use of its lead product, AMR101, in the treatment of patients with very high triglyceride levels (the population studied in Amarin's MARINE trial), and the FDA has assigned a Prescription Drug User Fee Act (PDUFA) date of July 26, 2012 for the completion of its review. Amarin plans to separately seek approval for use of AMR101 in the treatment of patients with high triglyceride levels who are also on statin therapy for elevated LDL-C levels, the population studied in the ANCHOR trial, if the FDA approves the MARINE indication and after the REDUCE-IT cardiovascular outcomes trial is substantially underway. In December 2011, Amarin commenced patient dosing in a cardiovascular outcomes study of AMR101, titled REDUCE-IT (Reduction of Cardiovascular Events with EPA — Intervention Trial). Each of the MARINE, ANCHOR and REDUCE-IT studies is the subject of a Special Protocol Assessment (SPA) agreement with the FDA. Amarin also has next-generation lipid candidates under evaluation in preclinical development.

### **Forward Looking Statements**

This press release contains forward-looking statements, including statements about the intention of the FDA to not convene an advisory committee to aid the FDA in its review of the AMR101 NDA, timing of FDA decisions regarding AMR101, the efficacy, safety and therapeutic benefits of AMR101 and the plans of Amarin to seek approval for its product candidates. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. Among the factors that could cause actual results to differ materially from those described or projected herein include the following: the FDA making a subsequent determination that an advisory committee would be appropriate for the review of the AMR101 NDA; uncertainties associated generally with research and development, clinical trials and related regulatory approvals; the risk that SPAs are not a guarantee that FDA will approve a product candidate upon submission; and the risk that historical clinical trial enrollment and randomization rates may not be predictive of future results. A further list and description of these risks, uncertainties and other risks associated with an investment in Amarin can be found in Amarin's filings with the U.S. Securities and Exchange Commission, including its most recent Annual Report on Form 10-K and its most recent Quarterly Report on Form 10-Q. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Amarin undertakes no obligation to update or revise the information contained in this press release, whether as a result of new information, future events or circumstances or otherwise.

Amarin's product candidates are in various stages of development and are not available for sale or use outside of approved clinical trials. Nothing in this press release should be construed as marketing the use of such product candidates.

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